

Attorney Docket No.: 6423.404-US
Filing Date: June 24, 2003

US Application No.: 10/602,838
Examiner: Silverman, Eric E.

REMARKS

Entry of this amendment is respectfully requested, as it is believed to place the claims in condition for allowance and would not require new search.

Reconsideration and allowance are respectfully requested.

Claims 1-19 and 21-37 are pending and at issue. In this response, claims 1, 30, and 31 are amended for further clarity and claims 27, 28 and 32-37 are cancelled without prejudice. Support for the amendments can be found in the specification as originally filed. For example, the specification at page 9, lines 5-15 discloses liquid formulations of Factor VII that are stable for at least 6 months when stored at 2-8°C. No new matter is added. Accordingly, claims 1-19, 21-26, and 29-31 are pending and at issue.

Rejections Under 35 U.S.C. § 112, First Paragraph

Claims 27 and 28 have been rejected under 35 U.S.C. § 112, first paragraph, as failing to comply with the written description requirement. The Examiner contends that the terms "Factor VIIa sequence variant" encompasses an unduly large number of species.

Applicants maintain that the present specification clearly indicates that Applicants had possession of a formulation that can be used with Factor VII sequence variants as well as wild-type Factor VII. Nonetheless, to advance prosecution claims 27 and 28 have been cancelled, rendering this rejection moot.

Rejections Under 35 U.S.C. § 112, Second Paragraph

Claim 17 has been rejected under 35 U.S.C. § 112, second paragraph, for indefiniteness, for the recitation of "methionine analogue".

As explained in the response filed August 7, 2006, Applicants believe that the term "methionine analogue" is well-known in the art. Nonetheless, to advance prosecution claim 17 has been amended to delete this term, rendering this rejection moot.

Attorney Docket No.: 6423.404-US
Filing Date: June 24, 2003

US Application No.: 10/602,838
Examiner: Silverman, Eric E.

Rejections Under 35 U.S.C. § 103

Claims 1-7, 9-16, 21-23, 25, 26, and 29-37 have been rejected under 35 U.S.C. § 103(a) as unpatentable over The Medicine Catalogue. The Examiner claims that it would be obvious to vary the concentrations of the components of the presently claimed formulation.

The present invention is directed to a stable liquid formulation of Factor VII. The presently claimed formulations exhibit at least 50% retention of bioactivity upon storage for 6 months at 2-8°C.

The Medicine Catalogue discloses a *single* formulation of Factor VII that was designed to be stored in a lyophilized form. Notably, the Medicine Catalogue states, "*Stability: The solution is chemically stable for 24 hours, but should be used immediately.*" The gap between a stability of, at best, 24 hours, as disclosed in the Medicine Catalogue, and the presently claimed 6 months means that one of ordinary skill in the art, based on this disclosure, could have no expectation of achieving the presently claimed long-term stability in an aqueous formulation. On this basis, it is respectfully submitted that the presently claimed formulations are non-obvious over the cited reference.

The Examiner has maintained the rejections of: claim 8 as unpatentable over the Medicine Catalogue in combination with WO 97/19687 (Miekka et al); claims 17-19 as unpatentable over the Medicine Catalogue in combination with Thatcher et al., US 5,830,852; and claim 24 as unpatentable over the Medicine Catalogue in combination with Osawa et al., US 5,993,795. In all of these rejections, the Examiner further contends that it would have been obvious to combine each of the cited disclosures with The Medicine Catalogue Factor VII formulation to achieve the presently claimed invention. These rejections are respectfully traversed.

As discussed above, it is believed that the present invention, as broadly claimed, is non-obvious over The Medicine Catalogue. None of the secondary references remedies the deficiencies of The Medicine Catalogue with respect to any of the supplemental individual components of the presently claimed formulations. Accordingly, it is respectfully submitted that the presently claimed invention is non-obvious over all of the cited references and that these rejections should be withdrawn.

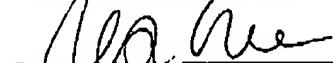
Attorney Docket No.: 6423.404-US
Filing Date: June 24, 2003

US Application No.: 10/602,838
Examiner: Silverman, Eric E.

In view of the above amendments and remarks, it is believed that the claims are in condition for allowance, and a determination to that effect is earnestly solicited.

Respectfully submitted,

Date: February 12, 2007


Reza Green, Reg. No. 38,475
Novo Nordisk Inc.
Customer Number 23650
(609) 987-5800

Use the following customer number for all correspondence regarding this application.

23650

PATENT TRADEMARK OFFICE